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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,382	03/31/2000	Alison A. McCormick	LSB-001/CIP	9680

7590 07/28/2004
DEAN H. NAKAMURA, ESQUIRE
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8A.

Office Action Summary

Application No.

09/539,382

Applicant(s)

MCCORMICK ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54,56,60-64,66,67,69,72,73 and 76-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54,56,60-64,66,67,69,72,73 and 76-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: McCormick *et al*
Priority Date: 24 September 1999

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/13/2004 has been entered.
2. Claims 1-53, 55,57-59,65,68,70-71, and 74-75 are canceled without prejudice or disclaimer.
3. Claims 54,56,60-64,66-67,69,72-73, and 76-86 are pending and examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 103

5. The rejection of claims 54,56,60-64,66-67,69,72-73 and 77-86 under 35 USC 103(a) as being obvious over Casper *et al* in view of Fiedler *et al* and Ladner *et al* is maintained for the reasons of record. Applicant's arguments are primarily drawn to the recited references lack of teaching concerning the means of making the antibody or the lack of functional activity (i.e. the ability to elicit an immune response). For example,

applicant argues that Casper *et al* fail to teach the production of the idiotype scFv in a plant cell, and that the scFv could not elicit an immune response in the absence of an adjuvant. However, the instant invention is drawn to a product *per se* and the method of making the product (i.e. in a plant cell) or the intended use (i.e. elicit an immune response) does not carry any weight in the determination of patentability. Applicant further argues that of all the references cited, Fiedler *et al* is the only one to provide any recitation of using plant cells, but differs from the instantly claimed invention because the nucleic acid sequence transfected into the plant cell is integrated into genome, while that instantly claimed is expressed in the cytoplasm via transient transfection. However, as stated above, the intended use of the product does not carry any patentable weight. In this case, whether the product is transiently transfected or stably integrated into the genome is irrelevant to the patent determination because the claims are still drawn to a product. Statements made by the applicant regarding the expression vectors ability to express "at all or in the same fashion" are unsubstantiated and are made without objective evidence, therefore these arguments are viewed as unpersuasive.

Applicant further argues that the linkers recited in the references are not randomized linkers, but rather conventional linkers. However, it was well known and established in the art that nucleic acid linkers serve the purpose of creating flexibility in a recombinantly expressed protein. However, if the use of conventional linkers failed to achieve the desired functionality, then the use of randomized linkers was also well known as evidenced by Tang Y *et al* (J Biol Chem. 1996 Jun 28;271(26):15682-6).

Therefore, given the fact that the references teach a nucleic acid molecule that encodes a B-cell lymphoma surface Ig antigen, and that the intended use or functionality does not breath any patentable weight into the claims, the rejection under 35 USC 103(a) is maintained for the reasons of record.

Claim Rejections Reinstated - 35 USC § 101

6. Upon further review and reconsideration, claims 54-63,72-76 and now claims 81-86 are rejected under 35 USC 101 because the claims were drawn to non-statutory subject matter. In a response filed 4/4/2003 applicant argued that the specifically claimed nucleic acid could not possibly be found in nature because the Vh and VI regions are either joined (i.e. claim 61 and 62) or comprised artificial linkers. The rejection under 35 USC 101 is withdrawn for claims 64, 66, 67 and 68, because they are drawn to subject matter that requires the "hand of man" (i.e. the use of randomized linkers), however, the remain rejected claims do not distinguish over product as they exist naturally. Furthermore, applicant states that claims 61 and 62 are "linked together", however this specific limitation is not found in the claims. Therefore the rejection under 35 USC 101 being drawn to non-statutory subject matter is maintained for the reasons of record.

New Arguments

Claim Rejections - 35 USC § 102

7. Claims 54,56,60-62,64,72-73,76, and 81-86 are rejected under 35 U.S.C. 102(a) as being anticipated by McCormick *et al* (Proc. Natl. Acad. Sci. USA January 1999; 96:703-708). McCormick *et al* teach a nucleic acid molecule encodes an scFv molecule

Art Unit: 1642

derived from a B-cell lymphoma surface antigen (see abstract). It is also disclosed that the nucleic acid molecules is infected into a tobacco plant via a plant virus, encodes a protein that is transiently produced in said tobacco plant, is capable of generating an anti-idiotypic antibody immune response, and wherein the scFv comprises both a Vh and VI domain (see pages 704-705). Because the scFv comprises both Vh and VI domains claims that read on a polynucleotide comprising at least two V regions are thereby anticipated. Furthermore, claims that read on eliciting an immune response or inducing a polyclonal anti-idiotypic antibody response (i.e. claims 72-73) are also anticipated because the claims are drawn to a product *per se*, and these functional limitations are inherent properties. Furthermore, because the Office does not have the facilities to determine whether the product of the prior art is capable of performing such functions, in the absence of factual evidence to the contrary, the product taught by McCormick *et al* would also have these properties. And lastly, McCormick *et al* teaches the administration of 15ug of the polypeptide antigen three times about two weeks apart (see page 705).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
July 22, 2004

A handwritten signature in black ink, appearing to read "Gary Nickol", with a stylized flourish at the end.

GARY NICKOL
PRIMARY EXAMINER